

### DETAILED ACTION

1. Acknowledgment is made of Applicant's amendment, which was received by the Office on October 22, 2009. Claims 8, 9, 39, 40, and 149 are cancelled. Claims 1-7, 10-38, 41-148, and 150-152 are currently pending. Claims 4-7, 14-38, and 41-148 are withdrawn.

#### *Election/Restrictions*

2. The restriction requirement between Group I (Claims 1-3, 10-13, and 150-152) and Group II (Claims 32-34, 41-44, 63-78, 150 and 151), as set forth in the Office action mailed on April 21, 2008, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 32-34, 41-44, 63-78, 150 and 151, directed to a system are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim (see below in this Office action).

In view of the above noted withdrawal of the restriction requirement, Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The restriction requirement between Group I (Claims 1-78), Group II (Claims 79-123, Group III (Claims 124 and 127-129), and Group IV (Claims 125-148), and among species I-VI, A-F, and 1-9 as set forth in the Office action mailed on September 23, 2005, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 4-7, 14-31, 35-38, and 45-62, directed to species I-VI, A-F, and 1-9 are no longer withdrawn from consideration because the claim(s)

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requires all the limitations of an allowable claim. However, Claims 79-148 directed to different methods remain withdrawn from consideration because they do not all require all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

5. Claims 1-7, 10-38, 41-78, and 150-152 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, with reference made to lines 20-23 of Claim 1 and lines 18-21 of Claim 32, it is sufficiently unclear whether the “one or more implantable leads providing for electrical connections” comprises a separate and distinct feature from the previously recited electrical wiring of the “controller” to the “gene regulatory signal delivery device” or if the “controller” is electrically wired to the “gene regulatory signal delivery device” through the “electrical connections” provided by the “one or more implantable leads”.

#### ***Allowable Subject Matter***

6. Claims 1-7, 10-31, and 150-152 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 32-34 and 41-78 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-36, 38-74, 76-78, and 96-113 of copending Application No. 10/890,825 (as amended November 6, 2009). Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the conflicting claims or an obvious variant thereof. For example, with respect to Claim 32 of the instant application, attention is directed to Claim 1 of Application No. 10/890,825 which also defines a system comprising: an implantable gene delivery device electrically wired to an implant controller of an implantable medical device via one or more implantable leads, wherein the implant controller is

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coupled to an event detector and an implant telemetry module and configured to produce an electrical signal to control gene delivery from the gene delivery device in response to a sensed predetermined cardiac condition detected by the event detector and an external command received by the implant telemetry module. Similar analysis may be applied to the remaining dependent claims of the current application upon simply inspection of the conflicting claims of copending Application No. 10/890,825 (as amended November 6, 2009).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JESSICA SARCIONE whose telephone number is (571)272-2129. The Examiner can normally be reached on Monday - Friday, 8:00 AM - 4:30 PM.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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March 13, 2010

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